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EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,545	Applicant(s) SAMUELS ET AL.
	Examiner Walter B Augenbaugh	Art Unit 1772

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The amendments made in claim 1 in the Amendment filed September 16, 2004 (Amdt. D) have been received and considered by Examiner.

Election/Restrictions

2. The restriction requirement is proper for the reasons provided in paragraph 3 of Paper 6 and in paragraph 4 of the Non-Final Rejection mailed April 16, 2004. The restriction requirement was made FINAL in Paper 6.

WITHDRAWN REJECTIONS

3. The 35 U.S.C. 103 rejections of claims 1-17, 32, 34 and 35 that were repeated in paragraphs 9-14 of the previous Office Action dated April 16, 2004 have been withdrawn due to Applicant's amendments in claim 1 in Amdt. D.

4. The 35 U.S.C. 103 rejection of claim 33 made of record in paragraph 15 of the previous Office Action dated April 16, 2004 has been withdrawn due to Applicant's amendments in claim 1 in Amdt. D.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

5. Claims 1-9, 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Campbell et al.

In regard to claims 1 and 2, Cook teaches a catheter balloon comprising a tubular elastic fabric structure (item 23, Fig. 2) that covers the inner layer (item 22, Fig. 2) of the balloon (item 12, Fig. 2) (col. 2, lines 29-45). Cook teaches that the fabric expands three dimensionally such

that an increase in diameter does not require a decrease in length of the balloon and contracts uniformly (col. 3, lines 46-62), and therefore teaches that the tubular elastic fabric structure of the balloon has a high degree of stretch and recovery in the circumferential direction.

Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns and that the tubular elastic fabric structure covers the outer surface of a balloon catheter.

Fowler et al., however, disclose a tubular elastic fabric structure of interconnected circumferential and longitudinal yarns (col. 3, lines 63-68 and col. 5, lines 30-47 and Fig. 2, 6 and 7). Fowler et al. disclose that the fabric has a uni-directional recovery force in the circumferential direction that results in the structure having a high degree of stretch and recovery in the circumferential direction while having no appreciable elongation at all in the longitudinal direction (col. 1, lines 34-61 and col. 3, lines 63-68). Fowler et al. disclose that the uni-directionality of the fabric is due to the manner in which the circumferential and longitudinal yarns are incorporated into the fabric (col. 1, lines 57-61). Fowler et al. teach that the circumferential yarns have stretch and recovery properties (since the circumferential yarns are elastomeric, see col. 2, lines 64-68) and that the longitudinal yarns have more resistance to stretch than the circumferential yarns (since Fowler et al. teach that the longitudinal yarns are non-stretch yarns, see col. 4, lines 27-37). Fowler et al. teach that the change in length in the longitudinal direction over the full range of stretch and recovery in the circumferential direction is less than 0.25 times the change in the diameter over the full range of stretch and recovery since Fowler et al. teach that when the longitudinal yarn is the non-stretch yarn, the tube expands radially but expands much less or not at all in the axial (i.e. longitudinal) direction (col. 4, lines

33-37). Therefore, one of ordinary skill in the art would have recognized to have replaced the elastic fabric structure of Cook with the elastic fabric structure of interconnected circumferential and longitudinal yarns of Fowler et al. in order to form a catheter balloon that has a unidirectional recovery force which enables the structure to have a high degree of stretch and recovery in the circumferential direction and no appreciable elongation at all in the longitudinal direction as taught by Fowler et al.

Campbell et al., furthermore, disclose a material that has similar mechanical properties to conventional percutaneous transluminal angioplasty (PTA) catheter balloons and the recovery characteristics of a latex balloon (col. 2, lines 44-55) that may be used as a complete, stand-alone balloon or as a cover for catheter balloons (col. 2, line 65-col. 3, line 2). Campbell et al. disclose that the balloon cover provides the covered balloon with the best features of PTA balloons, reduces the risk of rupture of an elastic balloon, contains the fragments of a ruptured balloon and increases the rate of deflation of PTA balloons (col. 3, lines 2-16). Campbell et al. disclose that the balloon cover (item 10, Fig. 3A) completely covers the balloon (item 25, Fig. 3A) and at least a portion of the catheter (item 11, Fig. 3A), and therefore that the cover is a balloon catheter cover. Therefore, one of ordinary skill in the art would have recognized to have used the balloon composite material taught by Cook and Fowler et al. as the material of a balloon catheter cover such as the balloon catheter cover of Campbell et al. since it is notoriously well known to those of ordinary skill in the art that a catheter balloon material can be used interchangeably as a complete, stand-alone balloon or as a cover for catheter balloons, so that the balloon is provided with the best features of PTA balloons, reduces the risk of rupture of an elastic balloon, contains the fragments of a ruptured balloon and increases the rate of deflation of PTA balloons (all

depending on whether the material is used as the balloon itself or as a balloon catheter cover) as taught by Campbell et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the elastic fabric structure of Cook with the elastic fabric structure of interconnected circumferential and longitudinal yarns of Fowler et al. in order to form a balloon catheter cover that has a unidirectional recovery force which enables the structure to have a high degree of stretch and recovery in the circumferential direction and no appreciable elongation at all in the longitudinal direction as taught by Fowler et al., and to have used the balloon composite material taught by Cook and Fowler et al. as the material of a balloon catheter cover such as the balloon catheter cover of Campbell et al. since it is notoriously well known to those of ordinary skill in the art that a catheter balloon material can be used interchangeably as a complete, stand-alone balloon or as a cover for catheter balloons, so that the balloon is provided with the best features of PTA balloons, reduces the risk of rupture of an elastic balloon, contains the fragments of a ruptured balloon and increases the rate of deflation of PTA balloons (all depending on whether the material is used as the balloon itself or as a balloon catheter cover) as taught by Campbell et al.

In regard to claims 3 and 4, Fowler et al. teach that the circumferential yarns have an elongation at break of more than 300% (col. 4, lines 55-56) and that the longitudinal yarns have an elongation at break of no greater than 50% (col. 4, lines 27-33), a range that falls within the claimed rim of limitations of less than 30%.

In regard to claim 5, Fowler et al. teach that the degree of stretch in the circumferential direction is such that the diameter of the cover when stretched is more than 2 times the diameter

of the cover when collapsed since Fowler et al. teach that the expansion of the radius of the tube is greater than 300% (col. 3, line 63-col. 4, line 5 and col. 6, lines 48-56).

In regard to claim 6, Fowler et al. teach that the degree of stretch is such that the diameter of the cover when stretched is more than 3 times the diameter of the cover when collapsed since Fowler et al. teach that the expansion of the radius of the tube is greater than 300% (col. 3, line 63-col. 4, line 5 and col. 6, lines 48-56).

In regard to claims 7-9, Fowler et al. teach that the longitudinal yarns are positioned at about zero degrees to the balloon axis and the circumferential yarns are positioned at about 90 degrees to the balloon axis (as claimed in claim 9) as clearly shown in Figures 2, 6 and 7, and therefore also at an angle of at least 70 degrees to the balloon axis (as claimed in claim 7) and at an angle greater than 85 degrees to the balloon axis (as claimed in claim 8).

In regard to claims 11-12, Fowler et al. teach that the expansible fabric can be woven, braided, weft knit or warp knit (col. 5, lines 30-33). In regard to claim 11, Fowler et al. teach an elastic tubular woven fabric wherein the circumferential yarns are filling yarns and the longitudinal yarns are warp yarns (col. 8, lines 47-51).

In regard to claim 13, Fowler et al. teach that the fabric is made in a flat form which is subsequently sewed to form the tubular shape (col. 5, lines 36-39). This teaching requires that the edges of the flat fabric are sewn together along the longitudinal direction of the tube as is claimed. Furthermore, the recitation "made by sewing edges of a flat fabric together so as to make a tube having a longitudinal dimension and a circumferential dimension, the edges being sewn together being along the longitudinal dimension" is a process limitation which has not been given patentable weight since the method of forming the balloon catheter cover is not germane to

the issue of patentability of the balloon catheter cover itself. The structure of the resultant balloon catheter cover recited by this process limitation, however, has been given patentable weight and has been addressed in the basis for rejection to claim 13 provided above.

In regard to claim 14, Fowler et al. teach that the elastomeric yarn is made from fibers of segmented polyurethane also known as spandex (col. 4, lines 55-60).

In regard to claim 17, Fowler et al. teach that the longitudinal yarns are made from any conventional yarn, preferably polyester or polyamide (col. 4, lines 48-54).

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Campbell et al. and in further view of Chaikof et al.

Cook, Fowler et al. and Campbell et al. teach the catheter balloon cover as discussed above. The circumferential yarns taught by Cook and Fowler et al. are elastomeric braiding yarns, and the longitudinal yarns taught by Cook and Fowler et al. are necessarily relatively stiff axial yarns, since elastomeric yarns are less stiff than nonelastomeric yarns. Fowler et al. teach that the expansible fabric can be woven, braided, weft knit or warp knit (col. 5, lines 30-33). Fowler et al. teach that the longitudinal yarns are axial yarns that resist stretching (col. 4, lines 27-37). Cook, Fowler et al. and Campbell et al. fail to explicitly teach that the fabric structure is a triaxial braid. Chaikof et al., however, teach that triaxially braided intraluminal tubular prostheses (col. 3, lines 51-65) that contain reinforcing longitudinal strands prevent the prostheses from contracting longitudinally (col. 8, lines 8-25). Therefore, one of ordinary skill in the art would have recognized to have triaxially braided the fabric since the triaxial braid structure prevents longitudinal contraction of the tubular braided structure as taught by Chaikof et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have triaxially braided the fabric since the triaxial braid structure prevents longitudinal contraction of the tubular braided structure as taught by Chaikof et al.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Campbell et al. and in further view of Gilding et al.

Cook, Fowler et al. and Campbell et al. teach the catheter balloon cover as discussed above. Fowler et al. teach that the elastomeric yarn is made from fibers of segmented polyurethane also known as spandex (col. 4, lines 55-60). Cook, Fowler et al. and Campbell et al. fail to explicitly teach that the segmented polyurethane of the spandex fiber is selected from the group consisting of polyetherurethaneurea and polyesterurethaneurea block copolymers or combinations thereof. Gilding et al., however, disclose a biomaterial formed from polyether urethane urea block copolymer "spandex" polymers (col. 5, lines 52-68). Therefore, one of ordinary skill in the art would have recognized to have formed the elastomeric yarns from polyether urethane urea block copolymers since polyether urethane urea block copolymers are biocompatible materials as taught by Gilding et al., which would therefore be used as a catheter balloon cover. Furthermore, note that Gilding et al. establish that segmented polyether urethane urea block copolymers are spandex polymers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the elastomeric yarns from polyether urethane urea block copolymers since polyether urethane urea block copolymers are biocompatible materials as taught by Gilding et al.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Campbell et al. and in further view of Zafiroglu.

Cook, Fowler et al. and Campbell et al. teach the balloon catheter cover as discussed above. Cook, Fowler et al. and Campbell et al. fail to teach that the elastomeric yarns are covered. Zafiroglu, however, discloses that covering an elastic yarn with a hard yarn improves stitching continuity and facilitates the use of very low tensions in the elastic feed yarns (col. 4, lines 41-46). Therefore, one of ordinary skill in the art would have recognized to have covered the elastomeric yarn of Cook and Fowler et al. with a hard yarn to improve stitching continuity and facilitate the use of very low tensions in the elastic feed yarns as taught by Zafiroglu.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have covered the elastomeric yarn of Cook and Fowler et al. with a hard yarn to improve stitching continuity and facilitate the use of very low tensions in the elastic feed yarns as taught by Zafiroglu.

9. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Fowler et al. and in further view of Campbell et al. and in further view of Killion et al.

Cook, Fowler et al. and Campbell et al. teach the catheter balloon cover as discussed above.

In regard to claim 32, Cook, Fowler et al. and Campbell et al. fail to explicitly teach that the properties vary along the length of the sleeve. Killion et al., however, teach an expandable stent that achieves a variation in radial force along the length of the stent by varying stent strut dimensions such as width, length, spacing and overall size (col. 2, lines 66-col. 3, line 27 and Figures 1. 6 and 7). Therefore, one of ordinary skill in the art would have recognized to have

varied the yarn spacing along the length of the tubular structure as Killion et al. vary the strut spacing of the stent long the stent in order to provide a tubular structure with expansion properties that vary along the length of the tubular structure as taught by Killion et al.

In regard to claim 33, Cook, Fowler et al., Campbell et al. and Killion et al. teach the balloon catheter cover as discussed above in regard to claim 32. Furthermore, Fowler et al. teach that the expansible fabric is braided (col. 5, line 30). Killion et al., however, teach that the expandable stent (of Killion et al.) achieves a variation in radial force along the length of the stent by varying stent strut dimensions such as width, length, spacing and overall size (col. 2, lines 66-col. 3, line 27 and Figures 1. 6 and 7). Therefore, one of ordinary skill in the art would have recognized to have varied the braiding yarn spacing along the length of the tubular elastic fabric structure taught by Cook and Fowler et al. as Killion et al. vary the strut spacing of the stent along the stent in order to provide a tubular elastic fabric structure with expansion properties that vary along the length of the tubular elastic fabric structure as taught by Killion et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the braiding yarn spacing along the length of the tubular elastic fabric structure taught by Cook and Fowler et al. as Killion et al. vary the strut spacing of the stent along the stent in order to provide a tubular elastic fabric structure with expansion properties that vary along the length of the tubular elastic fabric structure as taught by Killion et al.

Furthermore, the recitation "the varied properties along the length of the tubular elastic fabric structure are produced by varying the braiding yarn spacing along the length of the tubular elastic fabric structure" is a method limitation and therefore has been given little patentable

weight since the method of forming the cover is not germane to the issue of patentability of the cover itself.

In regard to claim 34, Cook, Fowler et al. and Campbell et al. fail to teach that the shape of the balloon catheter cover is not cylindrical. However, Killion et al. teach a stent that is tapered to conform to the interior of a narrowing vessel (col. 4, lines 29-41, col. 5, lines 15-24 and Figures 1 and 6). Therefore, one of ordinary skill in the art would have recognized to have formed the balloon catheter cover in a shape that is not cylindrical in order to form the balloon catheter cover in a tapered shape that would conform to the interior of a narrowing vessel since Killion et al. teach that it is notoriously well known to shape tubular intraluminal devices so that the shape of the device conforms to narrowing vessels.

In regard to claim 35, the recitation "the non-cylindrical shape is obtained by forming the cover over a shaped mandrel" is a method limitation and therefore has not been given patentable weight since the method of forming the cover is not germane to the issue of patentability of the cover itself.

ANSWERS TO APPLICANT'S ARGUMENTS

10. Applicant's arguments on pages 8-9 of Amdt. D regarding the applicability of the Cook and Fowler et al. patents have been fully considered but are not persuasive. The Office acknowledges that Cook fails to teach that the fabric structure is of interconnected circumferential and longitudinal yarns in the 35 U.S.C. 103(a) rejection of claim 1; this structure is taught by Fowler et al. for the reasons set forth in the 35 U.S.C. 103(a) rejection of claim 1. As stated in previous Office Actions, Cook and Fowler et al. constitute analogous art because both patents teach a cylindrical fabric structure that perform an equivalent mechanical function. The

subject matter claimed in claim 1 is taught by the combination of the Cook, Fowler et al. and Campbell et al. patents that is proposed in this Office Action.

11. In the first full paragraph of page 9 of Amdt. D., Applicant states "at paragraph 9 it is stated that claim 1 recites a method of forming the tubular elastic structure, rather than a specific structural feature of the invention". This is not stated or implied in paragraph 9 of the previous Office Action dated April 16, 2004. The second-to-last last sentence of paragraph 9 of the previous Office Action dated April 16, 2004 states that "the added recitation 'wherein the tubular elastic structure is formed' does not affect the claimed structure, composition or properties". Nothing in regard to "a method of forming the tubular elastic structure" is stated in paragraph 9 of the previous Office Action dated April 16, 2004. The structure recited by the phrase "wherein the tubular elastic structure is formed" was given full weight, but as stated in paragraph 9 of the previous Office Action dated April 16, 2004, this recitation "does not affect the claimed structure, composition or properties".

12. Applicant's arguments on page 10 of Amdt. D regarding the 35 U.S.C. 103(a) rejection of claim 33 have been fully considered but are not persuasive. Applicant argues that since the stents of Killion expand, Killion cannot be applied to reject the claimed catheter balloon cover since the cover "exerts radial force in an inward direction", but catheter balloons and catheter balloon covers also must expand when the balloons are inflated. See Cook and Campbell et al. Applicant argues that the "are produced by varying the braiding yarn spacing" recitation is not a method limitation since the recitation allegedly recites structure, but this recitation does not recite structure because structure of the final product is not positively recited: there is no requirement in the claim that the spacing that was varied during the "produc[tion]" of the cover exists in the

final product. The recitation "are produced by varying the braiding yarn spacing" is plainly a method limitation. The claim needs to be rewritten so that the structure of the final product is positively recited.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
11/24/04 WBA

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1772
11/26/04